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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/881,509	06/24/97	SCHENDEL	D P564-7015

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EXAMINER

DECLLOUX, A

ART UNIT

PAPER NUMBER

1644

29

DATE MAILED:

12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/881,509

Applicant(s)

Schendel

Examiner
DeCloux, Amy

Group Art Unit
1644



☒ Responsive to communication(s) filed on received 10-2-2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2 and 4-45 is/are pending in the application

Of the above, claim(s) 8-25 and 27-44 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2, 4-7, 26, and 45 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicant's final amendment, received 10-2-2000 (Paper No. 20), is acknowledged. However, the amendment to claim 4 has not been entered because said amendment directs the deletion of "1" and substitution of --2-- in line 1 of claim 4, however there is no "1" in line 1 of claim 4. For the purposes of examination, it is assumed that the applicant intends claim 4 to depend from claim 2.
2. Claims 2 and 4-45 are pending. Claims 8-25, and 27-44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 2, 4-7 and 26 and newly added claim 45 are being examined currently. Claim 26 is only being examined for the nucleic acid embodiment, since it was listed in the restriction as being in Groups I, II and III.
4. In view of applicant's arguments and amendment received 10-2-2000 (Paper No. 20), the 101 rejection and the 112 first rejections in Section 7B and 7C of the previous office action mailed 6/30/00 and the 112 2nd rejection have been withdrawn. However the written description 112 1st rejection has not been withdrawn, and a newly added 112 2nd rejection is made in response to the amendment to claim 4.
5. Applicant argues with respect to the 112 1st rejection that the instant claims are enabled for the broad recitation of "functional derivative" or any "fragment thereof" because the specification on page 10 describes the preparation of "functional derivatives" by means of recombinant DNA techniques and that on page 11 the preferred functional derivatives are single chain T cell receptors. However, it is noted that the latter are preferred embodiments only, and does not enable other embodiments of functional derivatives, since it is not disclosed how to make and use the derivatives except through the use of the generic term of recombinant DNA techniques. Therefore, there is insufficient guidance and direction of how to make and use said functional derivatives and fragments thereof.

Applicant's arguments have been carefully considered but are not deemed persuasive, and the rejection is maintained and applied to newly added claim 45, see below.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7A) Claims 2, 4-7, 26 and newly added claim 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid which codes for an alpha chain of the human T cell receptor comprising SEQ ID NO:23 where $X_1...X_n$ is one of the amino acid sequences recited in claims 3 and 4 of the instant application, a Fab, a single chain antibody, or soluble TCR fragments thereof, and a composition thereof, does not reasonably provide enablement for the broader recitation of any "functional derivative or any fragment thereof" or composition thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the nucleic acid that encodes for a human T cell receptor comprising SEQ ID NO:23, where $X_1...X_n$ is one of the amino acid sequences recited in claims 2 and 4 of the instant application, a Fab, a single chain antibody, or a soluble TCR fragment, or composition thereof, the specification fails to provide sufficient guidance in determining if a nucleic acid that encodes any derivative or any fragment of the recited alpha chain will encode an alpha chain of a T cell receptor (TCR) with the desired specificity. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids which code for a "functional derivative or fragment thereof" where the expectation of retaining similar encoding function is unpredictable based on the instant disclosure. Detailed information regarding the structural and functional requirements of the CDR3 region of an alpha TCR specific for kidney carcinoma, other than the CDR3 sequences recited in claims 2 and 4, is lacking. Also, recognition of a T cell epitope depends on the interaction of CDR3 with the MHC-peptide complex. Therefore, predicting that any functional derivative or any fragment thereof that would maintain the desired specificity is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the size and sequence of derivatives and fragments which preserve the TCR specificity, in order to make and use polynucleotides, probes, vectors, host cells and recombinant methods in a manner reasonably commensurate with the scope of the claims. Thus, it would require undue experimentation of one skilled in the art to practice the claimed invention. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claims 4-7 and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claim 4 and its dependent claims 4-7 and 26 are indefinite because it depends from claim 3 which has been canceled. It is noted that the amendment of claim 4 as directed in the amendment received 10-5-2000 has not been entered as discussed supra.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. This application contains claims drawn to an invention nonelected with traverse in Paper No. 17 received 4-19-00. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

- 13.. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the

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PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
December 11, 2000

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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